3. DISCUSSION OF SAFETY AND EFFECTIVENESS

A. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Model No. /Names:	MedX LPT 200 Tethered Laser & MedX LPS 200 Portable Laser
Classification:	Lamp Infrared, Heating Category ILY Physical Medicine Device, 21 CFR 890.5500 (Class II)
Predicate Devices:	MedX 1100 Console, LCS 100 Portable Laser and LCT 100 Tethered Laser (K032231)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Description of Devices

The MedX LPT 200 is a single diode, 200 mW tethered laser powered and controlled by the MedX 1100 Console. The MedX LPS 200 Portable Laser is a single diode, 200 mW laser that has embedded control and contains a rechargeable battery. The two devices have substantially equivalent output parameters. Both of these products use 808 nm near infrared laser diodes. Additionally these devices have been designed to produce therapeutic heating for the same indications of use as described in the ILY category. Therefore the requested indications of use for these two devices; when heat is indicated for the *temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, and minor pain and stiffness associated with arthritis.*

Both of the MedX Laser devices in this submission utilize a single semiconductor laser diode emitting approximately 200 mW (maximum + or – 10%) at the end of the fiber optic light guide. Both laser devices use 808 nm GaAlAs (gallium-aluminum-arsenide) laser diodes.

The LPS 200 Portable Laser produces only continuous mode light at 808 nm. The tethered MedX laser is powered by the MedX 1100 console and is capable of continuous duty cycle or pulsing at 8, 146 and 1000 Hz at 80% duty cycle. The console and portable automatically turns itself off after the set treatment time has been delivered.

Technological Characteristics Summary

The technological characteristics are a combination of the predicate Device – K032231. The indications for use are identical to these predicate products.

Testing for both the MedX 1100 Console and the tethered MedX LPT 200 Laser and the MedX 200 Portable Laser have been carried out in the following areas: mechanical, electrical, firmware, thermal safety, environmental conditions and electromagnetic compatibility, temperature control and irradiation distribution patterns. The MedX 1100 Console and both laser devices have been found to be safe in all areas for the intended use referenced in this submission.

Discussion of Non-Clinical and Clinical Data

Clinical practice in Canada has demonstrated the ability of the MedX 1100 Console and tethered laser device as well as the MedX 200 Portable Laser to warm the surface temperature and provide relief of minor aches and pains associated with minor muscle and tissue injury. Research was conducted for this specific 510(k) submittal specifically demonstrating heating. *See Appendix I for heat testing data.*

No new clinical trials were performed on the submitted products for this 510(k) submission. With over 30 years of research and clinical experience with therapeutic heating, the modality has demonstrated to be safe as adjunctive therapy where heating is indicated.

Conclusions Demonstrating Safety, Effectiveness and Performance

The testing carried out for the MedX LPT 200 powered and controlled by the MedX 1100 Console and the MedX 200 Portable Laser indicates that they meet design and performance functional requirements. Clinical practice and academic research demonstrate the successful use of the infrared lamp when heat is indicated for temporary increase in local blood circulation, temporary relief of minor aches and pains associated with minor muscle and minor joint pain associated with arthritis. The proposed device meets the requirements of international and US medical electrical equipment standards for safety, and key performance and safety requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 01 2008

MedX Electronics, Inc.
% Intertek Testing Services
Mr. Daniel W. Lehtonen
Senior Staff Engineer – Medical Devices
2307 East Aurora Road
Twinsburg, Ohio 44087

Re: K082707
Trade/Device Name: MedX LPT 200 Tethered Laser
MedX LPS 200 Portable Laser
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp.
Regulatory Class: II
Product Code: ILY
Dated: September 15, 2008
Received: September 16, 2008

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 STATEMENT OF INTENDED USE

510 (k) Number: _____

Device Names: **MedX LPT 200 Tethered Laser &**
MedX LPS 200 Portable Laser

Indications for Use

The MedX LPT 200 single diode tethered laser is a part of the infrared console system, as per 21 CFR 890.5500. The device is used when heat is indicated for temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, minor pain and stiffness associated with arthritis.

The MedX LPS 200 single diode Portable Laser is a rechargeable infrared device, as per 21 CFR 890.5500. The device is used when heat is indicated for temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, minor pain and stiffness associated with arthritis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082707

(Division Sign-off)
Division of General Restorative Devices
510(k) Number _____

Concurrence of CDRH, Office of Device Evaluation (ODE)